

## REMARKS

### *Status of the Application*

Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are pending.

### *Specification Amendments*

Applicants have amended the “Related Patent Application” information section on page 1 of the specification to correct a typographical error resulting from the Amendment filed on December 14, 2007. Specifically, the amendment to the specification seeks to correct the reference to U.S. Patent No. 6,129,930 which was incorrectly referred to as U.S. Patent No. 6,129,920 in the prior Amendment.

### *Claim Amendments*

A number of amendments have been made to claim 29. Specifically, the phrase “of treating cholesterol disorders” has been deleted and replaced with the phrase “for achieving a balanced lipid alteration in a patient in need of treatment thereof”. Support for “achieving a balanced lipid alteration” can be found in the specification at least on page 6, line 12 and line 23. Support for the phrase “patient in need of treatment thereof” can be found on at least pages 20 and page 24, line 9. Claim 29 has also been amended to recite the phrase “during the evening or at night”. Support for this phrase can be found in original claim 13. Claim 29 has also been amended to recite that the patient is orally administered “at least two” intermediate formulations comprising “500, 750” or 1000 mg. Support for the “at least two” and “500 and 750” can be found on at least page 20, lines 3-4. Claim 29 has also been amended to recite that the at least two formulations “are administered together to the patient”. Support for this amendment can also be found at least on page 20, lines 3-4.

Claims 34, 40 and 46 have been amended.

No new matter has been added as a result of any of these amendments.

### *Interview Summary*

Applicants would like to thank the Examiner for the in person interview conducted on April 1, 2008. During that interview, Applicant and the Examiner agreed to certain amendments to claim 29 to overcome the rejection of the claims in view of U.S. Patent No. 5,268,181 and to make the scope of the claims commensurate with the scope of the Bova Declaration submitted in the Amendment filed on December 14,

2007. The undersigned attorney would again like to thank the Examiner for her assistance and courtesies extended during this interview.

*Double Patenting*

Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,920<sup>1</sup>; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715; claims 1-21 of U.S. Patent No. 6,746,691; claims 1-28 of U.S. Patent No. 6,818,229; and claims 1-12 of U.S. Patent No. 7,011,848. Applicants respectfully traverse.

Applicants herewith enclose an executed terminal disclaimers for U.S. Patent Nos. 6,080,428, 6,129,930, 6,469,035, 6,406,715, 6,746,691, 6,818,229 and 7,011,848. Applicant encloses herewith the requisite terminal disclaimer fee associated with the filing of each of these terminal disclaimers. In view of the submission of these terminal disclaimers, Applicants submit that this rejection is now moot and should be withdrawn.

Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 15-42, 58, 63, 64 and 71-81 of co-pending application no. 10/444,145. Applicants respectfully traverse.

Applicants herewith encloses an executed terminal disclaimers for U.S. Patent Application No. 10/444,145. Applicant encloses herewith the requisite terminal disclaimer fee associated with the filing of this terminal disclaimer. In view of the submission of this terminal disclaimer, Applicants submit that this rejection is now moot and should be withdrawn.

Also, in response to the rejection of claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 as not being patentably distinct from claims 1-13 of U.S. Patent No. 6,080,428; claims 1-148 of U.S. Patent No. 6,129,930; claims 1-30 of U.S. Patent No. 6,469,035; claims 1-16 of U.S. Patent No. 6,406,715; claims 1-21 of U.S. Patent No. 6,746,691; claims 1-28 of U.S. Patent No. 6,818,229; and claims 1-12 of U.S. Patent No. 7,011,848, the Examiner has requested that Applicants state that the above patents were commonly owned at the time the invention was made. The undersigned attorney submits that the above-identified patents were commonly owned at the time the present application was made. Applicants believe that this information is

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<sup>1</sup> Applicant believes that the Examiner is referring to 6,129,930 and that this is simply a typographical error.

sufficient to respond to the Examiner's request. If the Examiner requires any additional information or has any questions regarding this matter, the Examiner is invited to contact the undersigned attorney.

*Claim Rejections – 35 U.S.C. Section 103(a)*

Claims 29, 30, 32, 34-36, 38, 40-42, 44, 46, 62 and 63 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over U.S. Patent No. 5,126,145 (Evenstad et al.) ("145") or U.S. Patent No. 5,268,181 to O'Neill et al. ("181"). Applicants respectfully traverse.

As discussed during Applicants' interview, Applicants have amended claim 29 to make it commensurate with the scope of the Bova declaration filed in the Amendment on December 14, 2007. In view thereof, Applicants submit that they have now effectively removed the '181 patent as a reference. With respect to the '145 patent, as also discussed during the interview, the '145 patent does not teach or disclose using the described 250, 500 or 750 formulations for treating any condition or disease. Moreover, the '145 patent does not teach orally administering to a patient once per day at night or during the evening at least two intermediate formulations to obtain a dose of at least 1500 mg for the purpose of achieving a balanced lipid alteration in said patient. Therefore, in view of the aforementioned arguments, this rejection is now believed to be moot and should be withdrawn.

**REQUEST FOR RECONSIDERATION**

Reconsideration and withdrawal of all claim rejections are respectfully requested. Applicants believe that the present application is in condition for allowance. Should the Examiner have any questions or would like to discuss any matters in connection with the present application, the Examiner is invited to contact the undersigned at

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